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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,076	06/06/2001	Chen W. Liaw	AREN-0239	6379

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/875,076	Applicant(s) Chen et al.
Examiner Prema Mertz	Art Unit 1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 27, 2002

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 77-99 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 77-99 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group XVIII (claims 37, 39-40) in Paper No.9, 12/27/02 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP. § 818.03(a)). Furthermore, Applicants cancellation of claims 1-76 and introduction of new claims 77-99 drawn to the elected invention, renders moot Applicants traversal of the restriction requirement.

Original claims 37, 39-40 have been canceled in Paper No.9, 12/27/02. New claims 77-99 are pending and under consideration by the Examiner.

Specification

2. Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

Applicants have not made specific reference to some earlier filed provisional applications, and have left blanks in the Cross Reference to related Applications on pages 1-2 in the instant application. It is clear from the declaration that Applicants intend to claim priority to the earlier filed provisional applications. Specific reference to these provisional applications should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. In the event that Applicants do not perfect the priority claim, the instant claims will be

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rejected under 35 U.S.C. 102(a) in the next Office action which does not prevent the Examiner from making the next Office action final.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed i.e. a more specific title that would identify the nucleic acid by the protein it encodes. It is suggested that the titled be amended to read approximately as follows: "nucleic acid encoding human G protein-coupled receptor".

4. The abstract of the disclosure is objected to because there is no mention in the abstract of polynucleotides encoding G-protein-coupled receptors. Correction is required. See MPEP. § 608.01(b).

Claim objections

5. Claim 87 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall not serve as a basis for any other multiple dependent claim. Here claim 86 from which claim 87 depends from, is a multiple dependent claim. See MPEP. § 608.01(n). Appropriate correction is requested.

Claim rejections-35 U.S.C. 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 77-99 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are drawn to a nucleic acid encoding a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as "hARE-2" (page 17, line 18), the instant invention is incomplete. The instant specification does not disclose any information regarding functional characteristics or the biological activity of the protein encoded by the instant nucleic acid of SEQ ID NO:19. While the specification on page 15, lines 14-23 describes that the human orphan GPCRs disclosed maybe used for the direct identification of candidate compounds as inverse agonists, agonists or partial agonists, there is no guidance given about which specific activity/activities the claimed polypeptide would be likely to have. The specification does not demonstrate that the claimed nucleic acid encodes the polypeptide actually displays any of these recited activities. In the absence of knowledge of the specific biological significance of the claimed nucleic acid encoding a protein of SEQ ID NO:20, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real world" use for the nucleic acid encoding the protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

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A protein of unknown function would have utility if it can be employed as an indicator of a diseased state or of the presence of a disorder. The only disclosed function for the protein encoded by the nucleic acid of the instant invention is that it can be used for screening candidate compounds for the direct identification of candidate compounds as inverse agonists, agonists or partial agonists (page 13, lines 18-25). Applicant is only required to identify one substantial credible utility and the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have “substantial utility” “where specific benefit exists in currently available form”. The employment of the protein encoded by the nucleic acid of the instant invention, for screening candidate compounds for the direct identification of candidate compounds as inverse agonists, agonists or partial agonists, is not a substantial or specific utility.

Applicants disclose in the specification that the claimed nucleic acid encodes a GPCR protein (page 17, lines 8-21). The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, the protein encoded by the claimed nucleic acid is found to be member of the GPCR family, the claimed protein would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the

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claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Claims 77-99 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed nucleic acid encoding a protein, therefore, there is no specific and substantial asserted utility or well established for the claimed nucleic acid encoding a protein. The fact that the claimed nucleic acid encodes a protein that has homology to a GPCR protein is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Claim rejections-35 U.S.C. 112, first paragraph

7. Claims 78-83, 85-91, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide set forth in SEQ ID NO:20, does not reasonably provide enablement for an isolated polynucleotide consisting essentially of a nucleotide sequence encoding a polypeptide of SEQ ID NO:20 and a polynucleotide consisting essentially of a nucleotide sequence of SEQ ID NO:19. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With respect to new claims 78 and 85, the specification does not enable an isolated polynucleotide "consisting essentially of" a nucleotide sequence encoding a polypeptide of SEQ ID NO:20 and a polynucleotide "consisting essentially of" a nucleotide sequence of SEQ ID NO:19. The specification does not enable the skilled artisan to make and/or use polynucleotides that have essentially the same nucleotide sequence as the one disclosed. The issue here is how substantial must the sequence identity be, and what nucleotides constitute this identity? The specification does not teach which residues can be conservatively substituted without affecting the functional activity of the protein. It is known to the skilled artisan that conservative amino acid substitutions outside of the active site of a protein will not affect the functional activity of the protein; however, amino acid substitutions, even conservative alterations, within the active site can inactivate the protein or change its functional activity. Absent the specific degree of sequence identity, it is unpredictable if the claimed nucleic acid encoding a protein would also possess the same activity as the polypeptide having the amino acid sequence of SEQ ID NO:20. Thus, without guidance as to which residues can be conservatively substituted, the skilled artisan would not be able to make and/or use polynucleotides consisting essentially of the same nucleotide sequence as the polynucleotide having the nucleotide sequence of SEQ ID NO:20.

Claims 79-83 and 86-91 are rejected as vague and indefinite insofar as they depend on the above claims for their limitations.

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Claim rejections-35 USC § 112, second paragraph

8. Claims 78-83, 85-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 78, 85 are rejected as vague and indefinite for reciting "consisting essentially of" because it is unclear how substantial the nucleotide sequence identity should be, is it 50% the same, 75% the same or something else?

Claims 79-83 and 86-91 are rejected as vague and indefinite insofar as they depend on the above claims for their limitations.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the

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Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 29, 2003